



CDOCKET NO.: BMS-0891/PH-7345-A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In Re Application of:

James R. McCarthy

Confirmation No.: 1709

Application No.: 09/995,159

Group Art Unit: 1624

Filing Date: November 27, 2001

Examiner: V. Balasubramanian

For: CRF RECEPTOR ANTAGONISTS AND METHODS RELATING THERETO

EXPRESS MAIL LABEL NO: EL 970385364 US
DATE OF DEPOSIT: October 9, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or

before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- ☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;
or

☐ The fee of **\$180.00** as set forth in § 1.17(p) is attached.

- ☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of **\$180.00** as set forth in § 1.17(p).

- ☐ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☒ Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- ☐ Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

EXCEPT THAT:

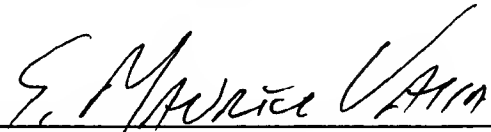
- ☒ In view of the voluminous nature of reference number 37, and the likelihood that this reference is available to the Examiner, copies are not enclosed herewith.
- ☒ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☒ Copies of references **1-8 and 51-52** listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No. **09/415,503 now U.S. Patent No. 6,352,990, filed October 8, 1999.**

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

- ☐ The relevance of those listed references which are not in the English language is as follows:
- ☒ There are no listed references which are not in the English language.

Date:

10/9/03


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Sheet 1 of 7

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. BMS-0891/PH-7345-A	Application No. 09/995,159	RECEIVED OCT 20 2003 TECH CENTER 1800/2900
	Applicant James R. McCarthy, et al.		
	Filing Date November 27, 2001	Group 1624	
	Confirmation No. 1709		
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	1	Adamiak, et al., <i>Angew. Chem.</i> , 1985 , 97(12), 1046 (CA 104:110099, 1986)	
	2	Brown, et al., <i>J. Chem. Soc.</i> , 1969 , C18, 2620-2624 (CA 72:21662, 1970)	
	3	Gundersen, et al., <i>Tetrahedron Letts.</i> , 1994 , 50(32), 9743-9756	
	4	Hamann, et al., <i>Can. J. Chem.</i> , 1968 , 46(3), 419-423 (CA 68:68957, 1968)	
	5	<i>J. Heterocycl. Chem.</i> , 1968 , 5(5), 679-682 (CA 70:4052, 1969)	
	6	McKenzie, et al., <i>J. Org. Chem.</i> , 1982 , 47(25), 4881-4884	
	7	Stevenson, et al., <i>Tetrahedron Letts.</i> , 1996 , 37(46), 8375-8378	
	8	Wang, et al., <i>Biochem. Pharmacol.</i> , 1979 , 28(15), 2249-2260 (CA 92:69336, 1980)	
	9	Al-Shaar. A..H., et al., "The synthesis of heterocycles via addition-elimination reactions of 4- and 5-aminoimidazoles," <i>J. Chem. Soc., Perkin Trans. 1</i> , 1992 , 2789-2793	
	10	Balicki, R., et al., Translocative rearrangements. Generality of the formamidine-induced rearrangement of 4-substituted 5-amino-4-cyano-4H-imidazoles," <i>J. Org. Chem.</i> , 1983 , 48(1), 3-7	
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Form PTO-1449 Modified

List of Patent and Publications
Cited by Applicant
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U.S. Department of Commerce
Patent and Trademark Office

Docket No.

BMS-0891/PH-7345-A

Application No.

09/995,159

Applicant

James R. McCarthy, et al.

Filing Date

November 27, 2001

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

11	Battaglia, G., et al., "Characterization of corticotrophin-releasing factor receptor-mediated adenylate cyclase activity in the rat central nervous system," <i>Synapse, Alan R. Liss, Inc.</i> 1987 , 1, 572-581
12	Bilezikjian, L.M., et al., "Glucocorticoids inhibit corticotrophin-releasing factor-induced production of adenosine 3',5'-monophosphate in cultured anterior pituitary cells," <i>Endocrinology</i> , 1983 , 113(2), 657-662
13	Boger, D.L., et al., "Inverse electron demand diels-alder reactions of heterocyclic aza dienes. Studies on the total synthesis of lavendamycin: investigative studies on the preparation of the CDE β -carboline ring system and AB quinoline-5,8-quinone ring system," <i>J. Org. Chem.</i> , 1985 , 50(26), 5782-5789
14	Borch, R.F., et al., "A new method for the methylation of amines," <i>J. Org. Chem.</i> , 1972 , 37(10), 1673-1674
15	Brown, M.R., et al., "Corticotropin-releasing factor: actions on the sympathetic nervous system and metabolism," <i>Endocrinology</i> , 1982 , 111(3), 928-931
16	Brown, et al., "Corticotropin-releasing factor: effects on the sympathetic nervous system and oxygen consumption," <i>Life Sciences</i> , 1982 , 30, 207-210
17	Chen, R., et al., "Expression cloning of a human corticotrophin-releasing-factor receptor," <i>PNAS, USA</i> , October 1993 , 90, 8967-8971
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20	Corey, E.J., et al., "A synthetic method for formyl \rightarrow ethynyl conversion ($RCHO \rightarrow RC\equiv CH$ or $RC\equiv CR'$)," <i>Tetrahedron Letts.</i> , 1972 , 36, 3769-3772

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	Filing Date November 27, 2001	Group 1624
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21	Crofford, L.J., et al., "Local secretion of corticotrophin-releasing hormone in the joints of lewis rats with inflammatory arthritis," <i>J. Clin. Invest.</i> , December 1992, 90, 2555-2564	
22	DeSouza, E.B., "Role of corticotrophin-releasing factor in neuropsychiatric disorders and neurodegenerative diseases," <i>Ann. Reports in Med. Chem.</i> , 1990, 25, Chapter 23, 215-223	
23	DeSouza, E.B., et al., "Corticotropin-releasing factor receptors in the pituitary gland and central nervous system: methods and overview," <i>Methods Enzymol.</i> , 1986, 124, 560-590	
24	DeSouza, E.B., et al., "Corticotropin-releasing factor receptors in rat forebrain autoradiographic identification," <i>Science</i> , June 1984, 224(4656), 1449-1451	
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26	Ehlers, C.L., et al., "Corticotropin releasing factor produces increases in brain excitability and convulsive seizures in rats," <i>Brain Res.</i> , 1983, 278, 332-336	
27	Estel, L., et al., "Metalation/S _{RN} 1 coupling in heterocyclic synthesis. A convenient methodology for ring functionalization," <i>J. Org. Chem.</i> , 1988, 53(12), 2740-2744	
28	Fisher, L.A., et al., "Corticotropin-releasing factor (CRF): Central effects on mean arterial pressure and heart rate in rats," <i>Endocrinology</i> , 1982, 110(6), page 2222	
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30	Irwin, M., et al., "CRF activates autonomic nervous system and reduces natural killer cytotoxicity," <i>Am. J. Physiol.</i> , 1988, 255(5), R744-R747	
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	33	Levine, A.S., et al., "Effect of centrally administered corticotrophin releasing factor (CRF) on multiple feeding paradigms," <i>Neuropharmacology</i> , 1983, 22(3A), 337-339
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	35	Perrin, M.H., et al., "Corticotrophin-releasing factor binding to the anterior pituitary receptor is modulated by divalent cations and guanyl nucleotides," <i>Endocrinology</i> , 1986, 118(3), 1171-1179
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	38	Rivier, J., et al., "Characterization of rat hypothalamic corticotrophin-releasing factor," <i>Proc. Natl. Acad. Sci. USA</i> , August 1983, 80, 4851-4855
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* A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and easily obtainable by the Examiner.



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	41	Shibahara, S., et al., "Isolation and sequence analysis of the human corticotrophin-releasing factor precursor gene," <i>EMBO J.</i> , 1983 , 2(5), 775-779		
	42	Sirinathsingji, D.J.S., et al., "Corticotropin-releasing factor is a potent inhibitor of sexual receptivity in the female rat," <i>Nature</i> , September 15, 1983 , 305, 232-235		
	43	Sutton, R.E., et al., "Corticotropin releasing factor produces behavioural activation in rats," <i>Nature</i> , May 27, 1982 , 297, 331-333		
	44	Tilders, F.J.H., et al., "Effect of hypothalamus lesions on the presence of CRF-immunoreactive nerve terminals in the median eminence and on the pituitary-adrenal response to stress," <i>Regul. Peptides</i> , 1982 , 5, 77-84		
	45	Udelsman, R., et al., "Functional corticotrophin releasing factor receptors in the primate peripheral sympathetic nervous system," <i>Nature</i> , January 9, 1986 , 319, 147-150		
	46	Vale, W., et al., "Characterization of a 41-residue ovine hypothalamic peptide that stimulates secretion of corticotrophin and β -endorphin," <i>Science</i> , September 1981 , 213, 1394-1397		
	47	Vita, N., et al., "Primary structure and functional expression of mouse pituitary and human brain corticotrophin releasing factor receptors," <i>FEBS</i> , November 1993 , 335(1), 1-5		
	48	Webster, E.L., et al., "Corticotropin-releasing factor receptors in mouse spleen: identification, autoradiographic localization, and regulation by divalent cations and guanine nucleotides," <i>Endocrinology</i> , 1988 , 122(2), 609-617		
	49	Williams, C.L., et al., "Corticotropin-releasing factor directly mediates colonic responses to stress," <i>Am. J. Physiol.</i> , 1987 , 253, G582-G586		
	50	Wynn, P.C., et al., "Properties and regulation of high-affinity pituitary receptors for corticotrophin-releasing factor," <i>Biochem. & Biophys. Res. Comm.</i> , January 27, 1983 , 110(2), 602-608		
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Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. BMS-0891/PH-7345-A	Application No. 09/995,159
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	Filing Date November 27, 2001	Group 1624
	Confirmation No. 1709	

U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	51	5,063,245	11/05/91	Abreu, et al.	514	404
	52	5,464,847	11/07/95	Courtemanche, et al.	514	342
	53	4,605,642	08/12/86	Rivier, et al.	514	12
	54	US 6,352,990 B1	03/05/02	McCarthy	514	261

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					YES	NO
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	56	0 773 023 A1	05/14/97	EPO		
	57	0 778 277 A1	06/11/97	EPO		
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U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	60	WO 94/13677	06/23/94	PCT		
	61	WO 95/33750	12/14/95	PCT		
	62	WO 95/34563	12/21/95	PCT		
	63	WO 96/35689	11/14/96	PCT		
	64	WO 97/29109	08/14/97	PCT		
	65	WO 98/08846	03/05/98	PCT		
	66	WO 98/08847	03/05/98	PCT		
	67	WO 98/03510	01/29/98	PCT		
	68	WO 98/35967	08/20/98	PCT		

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